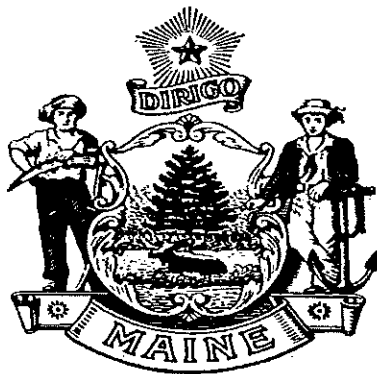


Rules Governing the Reporting of Sentinel Events

10-144 CMR Chapter 114

Effective Date: ~~April 17, 2010~~



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Purpose. The Regulations Governing the Reporting of Sentinel Events create a system for reporting all sentinel events to improve the quality of healthcare and increase patient safety. The reporting system focuses the attention of a healthcare facility on understanding the causes that underlie the event and on changing systems and processes to reduce the probability of future events.

Section 1. Definitions. As used in these rules, unless the context otherwise indicates, the following terms have the following meanings.

- 1.1 Adverse.** For the purposes of these rules, “adverse” means a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable.
- 1.2 Associated with.** For the purposes of these rules, “associated with” means that it is reasonable to initially assume that the adverse event was due to the referenced course of care; further investigation or root cause analysis of the unplanned event may be needed to confirm or refute the presumed relationship.
- 1.3 Disability.** “Disability” means a physical or mental impairment that substantially limits one or more of the major life activities of an individual. (see Americans with Disabilities Act).
- 1.4 Discovered.** For the purposes of these rules, “discovered” means the point at which one becomes aware of a sentinel event.
- 1.5 Division.** “Division” means the Department of Health and Human Services (DHHS), Division of Licensing and Regulatory Services (DLRS).
- 1.6 Event.** “Event” means a discrete, auditable, and clearly defined occurrence.
- 1.7 Final Agency Action.** “Final Agency Action” means a decision by DHHS which affects the legal rights, duties or privileges of specific persons, which is dispositive of all issues, legal and factual, and for which no further recourse, appeal or review is provided within DHHS, 5 M.R.S.A. §8002.
- 1.8 Healthcare Facility.** “Healthcare facility” or “facility” means a state institution as defined by 34-B M.R.S.A. Chapter 1 or a healthcare facility licensed by the division, excluding a facility licensed as a nursing facility by 22 M.R.S.A. Chapter 405 or licensed as an assisted housing program by 22 M.R.S.A. Chapter 1664. “Healthcare facility” includes:
 - 1.8.1** A general and specialty hospital licensed pursuant to 22 M.R.S.A. Chapter 405.

- 1.8.2 An ambulatory surgical facility licensed pursuant to 22 M.R.S.A. § 1812-E.
- 1.8.3 An end-stage renal disease (ESRD) facility licensed pursuant to 22 M.R.S.A. Chapter 412. These rules do not apply to home dialysis. Home dialysis means dialysis performed at home by an ESRD patient or caregiver who has completed an appropriate course of training.
- 1.8.4 An intermediate care facility for individuals who are intellectually disabled (ICF/IID)~~persons with mental retardation or developmental disabilities (ICF/MR)~~ licensed pursuant to 22 M.R.S.A. Chapter-405.
- 1.9 **Hyperbilirubinemia.** "Hyperbilirubinemia" means bilirubin levels greater than 30 mg/dl.
- 1.10 **Hypoglycemia.** "Hypoglycemia" means blood glucose levels less than 60 mg/dl.
- 1.11 **Immediate jeopardy.** "Immediate jeopardy" means a situation in which the provider's noncompliance with one or more conditions of participation in the federal Medicare program has caused, or is likely to cause, serious injury, harm or impairment to or death of a patient.
- 1.12 **Inter-facility transfer.** "Inter-facility transfer" means any transfer, after initial assessment and stabilization of the patient, from, and to, a healthcare facility, or within the same health system, including but not limited to:
 - 1.12.1 Hospital to hospital.
 - 1.12.2 Clinic to hospital.
 - 1.12.3 Hospital to rehabilitation facility.
 - 1.12.4 Ambulatory surgical facility to hospital.
 - 1.12.5 Hospital to long term care.
 - 1.12.6 ESRD to hospital.
- 1.13 **Major Life Activities.** For the purposes of these rules, "major life activities" means functions, including but not limited to, caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, lifting, bending, speaking, breathing, learning, reading, concentrating, thinking, communicating, working and the operation of a major bodily function. Major bodily functions include but are not limited to functions of the immune system, normal cell growth, digestive, bowel, bladder, neurological, brain,

respiratory, circulatory, endocrine, and reproductive functions. (see the federal Americans with Disabilities Act).

1.14 Major Permanent Loss of Function. “Major permanent loss of function” means sensory, motor, physiological or intellectual impairment that was not present at the time of admission and

1.4.1 requires continued treatment or

1.4.2 imposes persistent major restrictions in activities of daily living; and

1.14.3 is unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition in a health care facility.

1.15 Near Miss Event. “Near miss” means an event or situation that did not produce patient injury, but only because of chance, which may include, but is not limited to, robustness of the patient or a fortuitous, timely intervention.

1.16 Neonate. “Neonate” means the first 28 days of life.

1.17 Perinatal Period. “Perinatal period” means the 28th week of gestation to the 28th day of life.

1.18 Pregnancy, High Risk. “High risk pregnancy” means a pregnancy in which the mother or the developing fetus has a condition that places one or both of them at a higher-than-normal-risk for complications, either during the pregnancy (antepartum), during delivery (intrapartum), or following the birth (postpartum).

1.19 Pregnancy, Low Risk. “Low risk pregnancy” means a pregnancy occurring in a woman aged 18-39 who has no previous diagnosis of essential hypertension, renal disease, collagen vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome.

1.20 Preventable. For the purposes of these rules “preventable” means an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure.

1.21 Root Cause Analysis (RCA). “Root cause analysis” means a structured process for identifying the causal or contributing factors underlying adverse events. The RCA follows a predefined protocol for identifying the specific factors in causal categories.

1.22 Sentinel Event. A “sentinel event” means:

- 1.22.1** An unanticipated death, or patient transfer to another health care facility, unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition in a health care facility;
- 1.22.2** A major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition in a health care facility that is present at the time of the discharge of the patient.
 - 1.22.2.1** For the purposes of ESRDs, the term “discharge” means within 48 hours of a treatment.
 - 1.22.2.2** If within 14 days of discharge from the facility, evidence is discovered that the major loss of function was not permanent, the health care facility is not required to submit a report pursuant to 22 M.R.S.A. § 8753 (2);
- 1.22.3** An unanticipated perinatal death or major permanent loss of function in an infant, with a birth weight over 2,500 grams that is unrelated to the natural course of the infant's or mother's illness or underlying condition or unrelated to the proper treatment of the infant's or mother's illness or underlying condition in a healthcare facility; and
- 1.22.4** Other serious and preventable events described in this section or Appendix ~~1A~~ of these rules pursuant to 22 M.R.S.A. §8752 (4-A) (D).

Incorporation By Reference. Appendix ~~1A~~ incorporates by reference “~~Table 1—List of Serious Reportable Events, pages 7-16~~” of the National Quality Forum (NQF), *~~Serious Reportable Events in Healthcare—2006 Update: A Consensus Report.~~* “Specifications of the Serious Reportable Events in Healthcare – 2011 Update” of the National Quality Forum (NQF). See 5 M.R.S.A. §8056(1)(B)(1).

Exception: Appendix A does not apply to Maine's licensed nursing facilities or licensed assisted housing programs. Healthcare facilities that are subject to these rules are defined in Section 1.8 of these rules.

Copies of Incorporated Matter Available. In addition to its availability in Appendix ~~1A~~ of these rules, copies of “~~Table 1—List of Serious Reportable Events, pages 7-16~~” of the National Quality Forum (NQF), *~~Serious Reportable Events in Healthcare—2006 Update: A Consensus Report.~~* “Specifications of the Serious Reportable Events in Healthcare – 2011 Update” may be found at

<http://www.qualityforum.org/Topics/Safety.aspx>

http://www.qualityforum.org/projects/hacs_and_sres.aspx or may be obtained at cost from the Maine DHHS, Division of Licensing and Regulatory Services, 11 State House Station, Augusta, Maine 04333.

Failure to Comply is Violation of Rules. Failure to comply with the specifications and guidance in ~~“Table 1—List of Serious Reportable Events, pages 7-16”~~ of the National Quality Forum (NQF), ~~*Serious Reportable Events in Healthcare—2006 Update: A Consensus Report*~~ in Appendix 1A ~~“Specifications of the Serious Reportable Events in Healthcare – 2011 Update”~~ constitutes a violation of these rules.

1.22.4.1 Surgical Events

- 1.22.4.1.1. Surgery performed on the wrong body part.
- 1.22.4.1.2. Surgery performed on the wrong patient.
- 1.22.4.1.3. Wrong surgical procedure performed on a patient.
- 1.22.4.1.4. Unintended retention of a foreign object in a patient after surgery or other procedure.
- 1.22.4.1.5. Intraoperative or immediately postoperative death in an ASA Class 1 patient. ASA Class 1 patient is an acronym for “American Society of Anesthesiologists Classification 1 (Normal Healthy Patient)”.

1.22.4.2 Product or Device Events

- 1.22.4.2.1. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility.
- 1.22.4.2.2. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended.
- 1.22.4.2.3. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility.

1.22.4.3 Patient Protection Events

- 1.22.4.3.1 Infant discharged to the wrong person.
- 1.22.4.3.2 Patient death or serious disability associated with patient elopement (disappearance).
- 1.22.4.3.3 Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility.

1.22.4.4 Patient Treatment Events

- 1.22.4.4.1 Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration).
- 1.22.4.4.2 Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products.
- 1.22.4.4.3 Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility.
- 1.22.4.4.4 Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility.
- 1.22.4.4.5 Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates.
- 1.22.4.4.6 Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility.
- 1.22.4.4.7 Patient death or serious disability due to spinal manipulative therapy.
- 1.22.4.4.8 Artificial insemination with the wrong donor sperm or wrong egg.

1.22.4.5 Environmental Events

- 1.22.4.5.1 Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility.
- 1.22.4.5.2 Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.
- 1.22.4.5.3 Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility.
- 1.22.4.5.4 Patient death or serious disability associated with a fall while being cared for in a healthcare facility.
- 1.22.4.5.5 Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility.

1.22.4.6 Criminal Events

- 1.22.4.6.1 Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.
- 1.22.4.6.2 Abduction of a patient of any age.
- 1.22.4.6.3 Sexual assault on a patient within or on the grounds of a healthcare facility.
 - 1.22.4.6.3.1 If *one or more* of the following criteria is met, the facility is required to submit notification regarding a sexual assault:
 - 1.22.4.6.3.2 Any staff-witnessed sexual assault.
 - 1.22.4.6.3.3 Sufficient clinical evidence obtained by the healthcare facility to support allegations of sexual assault.
 - 1.22.4.6.3.4 Admission by the perpetrator of a sexual assault that occurred on the premises.

1.22.4.6.4 Death or a significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility.

- 1.23 Sentinel Events Team.** The Sentinel Events Team (SET), a unit of the Division of Licensing and Regulatory Services (DLRS), is assigned the responsibility to implement these rules.
- 1.24 Serious.** For the purposes of these rules, “serious” means an event that results in death or loss of a body part, disability or loss of bodily function lasting more than seven days or still present at the time of discharge from a facility or requires major intervention for correction including but not limited to higher level of care or surgery, ~~when referring to other than an adverse event, an event the occurrence of which is not trivial.~~
- 1.25 Sexual Assault.** “Sexual assault” as a reportable event means nonconsensual sexual contact that is not part of medically necessary health care involving a patient and another patient, staff member, or other perpetrator while being treated or on the premises of the healthcare facility, including oral, vaginal or anal penetration or fondling of the patient’s sex organ(s) by another individual’s hand, sex organ or object.
- 1.26 Spinal Manipulative Therapy.** “Spinal manipulative therapy” means all types of manual techniques, including spinal mobilization (movement of a joint within its physiologic range of motion) and manipulation (movement beyond its physiologic range of motion), regardless of their precise anatomic and physiologic focus or their discipline of origin.
- 1.27 Surgery.** “Surgery” means an invasive operative procedure, including a minimally invasive procedure, in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice.

Section 2. Facility Responsibilities.

2.1 Notification and Reporting System. A health care facility must have a Sentinel Event Notification and Reporting System as part of its hospital-wide, integrated patient safety program for all departments, programs, and services within the facility that includes but is not limited to:

2.1.1 Discovery System. Each health care facility shall have policies and procedures for identifying a sentinel event (Section 1.22). The written policies and procedures must include but not limited to the following:

2.1.1.1 Copy of the current Sentinel Events Reporting law, 22 M.R.S.A. Chapter 1684.

2.1.1.2 Copy of the current Rules Governing the Reporting of Sentinel Events, 10-144 C.M.R. Ch. 114.

2.1.1.3 Procedures for preservation of evidence, including but not limited to the following:

2.1.1.3.1 Procedure for sequestering equipment involved in the event.

2.1.1.3.2 Procedure for sequestering other evidence including but not limited to medication vials and intravenous (IV) administration bags.

2.1.1.3.3 Procedure for identifying clinical indications for requesting an autopsy.

2.1.1.4 Procedure for periodically reviewing a sample of death logs, transfer logs, patient complaints, patient records submitted for case review, resuscitation reviews and other records as a quality assurance mechanism to assure that cases are being identified and reported.

2.1.1.5 Procedure for communicating the definition of a sentinel event throughout the organization.

2.1.2 Notification Policy. Facility sentinel event notification policies and procedures shall include but are not limited to the following:

2.1.2.1 Facility procedure for notifying the SET.

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Section 3. Standardized Procedures.

3.1 Notification by next business day. The healthcare facility must notify the SET of a sentinel event (Section 1.22) by the next business day after the event occurred or the next business day after the facility discovers that the event occurred. The notification must include but is not limited to the date and time of notification, the name of the health care facility, the type of sentinel event, and the date and time the sentinel event occurred.

3.2 Notification Procedure. Immediately upon discovery of a sentinel event, the facility must act in accordance with its notification procedures as required by Section 2.1 of these rules.

3.2.1 Notification of the discovery of a sentinel event must not be delayed secondary to internal deliberations or pending autopsy or medical examiner results.

3.2.2 Within 1 business day of the discovery of a sentinel event, the healthcare facility must send the department-approved sentinel event notification form to the SET by facsimile or encrypted e-mail.

3.3 Situational Notification Considerations.

3.3.1 Inter-facility Transfer Notification. A sending facility is required to submit to the SET notification regarding a sentinel event when the transfer to another facility is unrelated to the natural course of the patient's illness or underlying condition; or unrelated to the proper treatment of that illness or underlying condition in its healthcare facility.

3.3.2 Discharge Follow-up Notification.

3.3.2.1 A facility is required to submit to the SET notification by the next business day after the event occurred or the next business day after the facility discovers that the event occurred regarding a sentinel event involving a patient with a major permanent loss of function that is present at the time of discharge that is unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition in a health care facility.

3.3.2.1.1 If within 14 days of discharge from a health care facility, evidence is discovered that the major loss of function was not permanent, the facility must submit the department-approved Functional Evidence form with supporting documentation to the SET, and the health care facility is not required to submit a report

pursuant to 22 M.R.S.A. § 8753 (2).

3.3.2.2 A facility is required to submit to the SET notification by the next business day after the event occurred or the next business day after the facility discovers that the event occurred when a sentinel event involving a death or major permanent loss of function occurs within 48 hours of treatment or procedure in an emergency department, ambulatory surgical facility, or end stage renal disease facility that is unrelated to the natural course of the patient's illness or underlying condition; or unrelated to the proper treatment of that illness or underlying condition in a healthcare facility.

3.3.2.3 A facility is required to submit to the SET notification by the next business day after the event occurred or the next business day after the facility discovers that the event occurred when the suicide of a patient occurs within 48 hours of discharge from a healthcare facility.

3.4 SET Case Review. Upon receipt of a notification or report of a sentinel event, the SET completes an initial review and may take other action that it determines to be appropriate pursuant to these rules. The facility must comply with the following requirements for the SET case review:

3.4.1 Provide a copy of the patient's medical record.

3.4.2 Provide a timeline of the event.

3.4.3 Present details of the event.

3.4.4 Schedule SET conference with the CEO or Administrator.

3.4.5 Schedule SET de-briefing regarding the findings with the facility.

3.5 Immediate Jeopardy. The division personnel responsible for sentinel event oversight shall report to the division's licensing section only incidences of immediate jeopardy and each condition of participation in the federal Medicare program related to the immediate jeopardy for which the provider is out of compliance.

Section 4. Root Cause Analysis (RCA).

- 4.1 RCA Required.** The healthcare facility is required to submit to the SET a thorough and credible root cause analysis no later than 45 days after notification of the sentinel event. The RCA may exclude protected professional competence review information pursuant to the Maine Health Security Act.
- 4.2 RCA Report.** The RCA must be submitted in an envelope labeled 'confidential' and the written report must contain at least the following:
- 4.2.1** Facility-specific unique identifier provided by the SET.
 - 4.2.2** The root cause analysis.
 - 4.2.3** Signature of the chief executive officer (CEO) of the facility.
 - 4.2.4** Other information significant to the identification of systems improvements with the goal being prevention of the recurrence of a similar sentinel event, including but not limited to the following:
 - 4.2.4.1** The final timeline of events.
 - 4.2.4.2** Identification of the occurrence of a similar event or events.
 - 4.2.4.3** Evidence of evaluation of the corrective actions implemented as a result of the similar event or events,
 - 4.2.4.4** Evidence of communication with the receiving facility in the event of an inter-facility transfer.
 - 4.2.4.5** An action plan that includes at least the following:
 - 4.2.4.5.1** Where improvement actions are planned, identification of who is responsible for implementation, when the action will be implemented (including any pilot testing), and how the effectiveness of the action will be evaluated.
 - 4.2.4.5.2** Identification of actions and rationale that clearly and specifically address each proximal cause and contributing factor of the sentinel event.
- 4.3 Thorough and Credible RCA.** An acceptable RCA must comply with the following:

- 4.3.1 A *thorough* root cause analysis includes at least the following information:
- 4.3.1.1 A determination of the human and other factors most directly associated with the sentinel event and the processes and systems related to its occurrence;
 - 4.3.1.2 An analysis of the underlying systems and processes to determine where redesign might reduce risk;
 - 4.3.1.3 An inquiry into all areas appropriate to the specific type of event;
 - 4.3.1.4 An identification of risk points and their potential contributions to the event;
 - 4.3.1.5 A determination of potential improvement in processes or systems that would tend to decrease the likelihood of such an event in the future or a determination, after analysis, that no such improvement opportunities exist;
 - 4.3.1.6 An action plan that identifies changes that can be implemented to reduce risks or formulates a rationale for not undertaking such changes; and,
 - 4.3.1.7 Where improvement actions are planned, an identification of who is responsible for implementation, when the action will be implemented and how the effectiveness of the action will be evaluated.
- 4.3.2 A *credible* root cause analysis meets the following criteria:
- 4.3.2.1 It includes participation by the leadership of the healthcare facility and by the individuals most closely involved in the processes and systems under review;
 - 4.3.2.2 It is internally consistent (that is, not contradict itself or leave obvious questions unanswered);
 - 4.3.2.3 It provides an explanation for all findings, including those identified as “not applicable” or “no problem,” and
 - 4.3.2.4 It includes the consideration of any relevant literature.
- 4.4 **Additional Information.** The SET may request additional information regarding the RCA and action plan, and the facility must comply as follows:

- 4.4.1** The facility must submit its written response to the SET written request for additional information within 14 days of receipt of the request, and the response must be signed by the Chief Executive Officer.

Section 5. Near Miss Events.

- 5.1 Voluntary Self-Reporting.** A healthcare facility may notify the SET of the occurrence of a near miss event (Section 1.15). Reports shall be made on department-approved forms and include requested documentation. 22 M.R.S.A. Sec. 8753 (5).
- 5.2 Report.** The Sentinel Events Annual Report shall include near miss aggregate data analysis for near miss detection methodologies, causative factors and safety improvements.

Section 6. Consumer Complaints: SET Compliance Review.

- 6.1 Complaints.** Any person with a licensing complaint may contact the division's Intake and Complaints Unit at 1-800-383-2441. If, upon review, the division determines that the reported event constitutes a sentinel event, it is referred to the SET.
- 6.2 SET On-site review.** The SET may conduct an announced and unannounced visit to any facility to achieve the following:
- 6.2.1** Determine compliance with these rules.
 - 6.2.2** Perform reviews based on complaints received by the division.
 - 6.2.3** Perform reviews based on third-party case identification.
 - 6.2.4** Review documents including but not limited to medical records, RCA reports, and committee meeting minutes. Professional competence review information protected pursuant to the Maine Health Security Act is excluded.

Section 7. Confidential and Privileged Information.

- 7.1 Confidential and privileged information.** Communication with the division is privileged and confidential.
- 7.1.1** The division shall take appropriate measures to protect the security of any information to which these rules apply.
- 7.1.1.1 Consultants.** When consultants are retained by the SET they shall be held to the same standards regarding confidentiality and privileged information.
- 7.1.2** Notifications and reports concerning sentinel events, near miss events, and suspected sentinel events filed pursuant to these rules and all information collected or developed as a result of the filing and proceedings pertaining to the filing, regardless of format, are confidential and privileged information.
- 7.1.3** Pursuant to these rules, privileged and confidential information is not:
- 7.1.3.1** Subject to public access under Title 1 M.R.S.A. Chapter 13, except for data developed from the reports that do not identify or permit identification of the healthcare facility;
- 7.1.3.2** Subject to discovery, subpoena or other means of legal compulsion for its release to any person or entity; or
- 7.1.3.3** Admissible as evidence in any civil, criminal, judicial or administrative proceeding.
- 7.1.4** Pursuant to these rules, the transfer of any information by a healthcare facility to the division or to a national organization that accredits healthcare facilities may not be treated as a waiver of any privilege or protection established by applicable Maine laws.
- 7.1.5** These rules may not be construed to limit other privileges that are available under federal or other laws of this State that provide for greater peer review or confidentiality protections than the peer review and confidentiality protections provided by these rules.
- 7.1.6** For the purposes of these rules, “privileged and confidential information” does not include:
- 7.1.6.1** Any final administrative action;

- 7.1.6.2 Information independently received pursuant to a third party complaint investigation conducted pursuant to department rules; or
- 7.1.6.3 Information designated as confidential under the rules and laws of this State.

7.2 Federal law. These rules do not affect the obligations of the department relating to federal law.

Section 8. Enforcement.

- 8.1 Immunity.** A person who in good faith reports a near miss event, a suspected sentinel event or a sentinel event or provides a RCA pursuant to these rules is immune from any civil or criminal liability for the act of reporting or participating in the review conducted by the SET.
- 8.1.1** “Good faith” does not include instances when a false report is made and the person reporting knows the report is false. These rules may not be construed to bar civil or criminal action regarding perjury or regarding the sentinel event that led to the report.
- 8.2 Financial Penalty.** When the division determines that a healthcare facility failed to report a sentinel event as required by these rules, the healthcare facility is subject to a financial penalty, payable to the State of Maine, of not more than \$10,000 per violation.
- 8.2.1** Each failure to report is a separate violation.
- 8.2.2** If a facility in good faith notified the division of a suspected sentinel event and the division later determines it is a sentinel event, the facility is not subject to a penalty for that event.
- 8.2.3** Funds collected pursuant to these rules must be deposited in a dedicated special revenue account to be used to support sentinel event reporting and education.
- 8.3 Notice of Imposition of Penalty.** The SET shall send written notice to the healthcare facility stating the amount of the financial penalty imposed for failure to report a sentinel event. The notice shall include but is not limited to the date of the event and the deadline for filing an appeal of the penalty.
- 8.3.1** Payment of the penalty is due within 10 days of receipt of the written notice of imposition of a penalty or the date of final agency action, whichever is later.
- 8.4 Administrative Hearing.** To contest the imposition of a penalty, a healthcare facility must submit to the division a written request for an administrative hearing within 10 days of receipt of the notice of imposition of a penalty.
- 8.5 Judicial Review.** Judicial appeal must be in accordance with 5 M.R.S.A. chapter 375, subchapter 7.
- 8.6 Injunction to require compliance.** Notwithstanding any other remedies provided by law, the Office of the Attorney General may seek an injunction to require compliance with the provisions of these rules.

- 8.7 District Court Complaint for violations.** The Office of the Attorney General may file a complaint with the District Court seeking injunctive relief for violations of these rules.

Statutory Authority

22 M.R.S.A. Chapter 1684

22 M.R.S.A. §42

22-A M.R.S.A. §205

Regulatory History

Public Law 2001, chapter 678, established laws governing the reporting sentinel events and instructed the department to adopt rules to implement chapter 678.

ADOPTED

Deleted sentinel events reporting provisions in the following:

- | | |
|-----------------------|--|
| 10-144 C.M.R. Ch. 112 | Regulations for the Licensure of General and Specialty Hospitals in the State of Maine. |
| 10-144 C.M.R. Ch. 118 | Regulations Governing the Licensing and Functioning of Intermediate Care Facilities for Persons with Mental Retardation. |
| 10-144 C.M.R. Ch. 125 | Regulations Governing the Licensing of Ambulatory Surgical Facilities. |
| 10-144 C.M.R. Ch. 126 | Regulations Governing the Licensing and Functioning of End Stage Renal Disease Units/Facilities. |

ADOPTED

[New] 10-144 C.M.R. Chapter 114, Rules Governing the Reporting of Sentinel Events, replaces the sentinel events reporting provisions in 10-144 C.M.R. Chapters 112, 118, 125, and 126.

EFFECTIVE DATE:

January 1, 2009 – filing 2008-579

AMENDED

April 17, 2010 – filing 2010-141

AMENDED

Appendix A - Specifications of the Serious Reportable Events In Healthcare—2011 Update

I. SURGICAL OR INVASIVE PROCEDURE EVENTS

Event: 1A. Surgery or other invasive procedure performed on the wrong site

Additional Specifications: Defined as any surgery or other invasive procedure performed on a body part or site that is not consistent with the correctly documented informed consent for that patient.

Surgery or other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, injection into joints.

Excludes emergent situations that occur in the course of surgery or other invasive procedure and/or whose exigency precludes obtaining informed consent.

Implementation Guidance: It should be noted that a correctly documented informed consent for patients whose procedures will not be carried out in an operating room may not involve a "surgical consent form"; however, it does require informed consent be documented in the patient record.

Although an incorrectly placed surgical mark could result in surgery being performed on the wrong body part, surgery does not begin at time the surgical mark is made on the patient. Placing a mark on the wrong body part or site does not in itself constitute wrong site surgery.

Wrong site surgery or invasive procedure, corrected during the procedure, is still a wrong site procedure if the surgery/procedure had begun, based on the definition in glossary.

This event is intended to capture instances of:

- surgery or other invasive procedure on the right body part but on the wrong location/site on the body; e.g., left/right (appendages/organs), wrong digit, level (spine), stent placed in wrong iliac artery, steroid injection into wrong knee, biopsy of wrong mole, burr hole on wrong side of skull;
- delivery of fluoroscopy or radiotherapy to the wrong region of the body;
- use of incorrectly placed vascular catheters;
- use of incorrectly placed tubes (for example, feeding tubes placed in the lung or ventilation tubes passed into the esophagus).

This event is not intended to capture:

- changes in plan upon entry into the patient with discovery of pathology in close proximity to the intended place where risk of a second surgery or procedure outweighs benefit of patient consultation, or unusual physical configuration (for example adhesions, spine level/extra vertebrae).

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

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1. SURGICAL OR INVASIVE PROCEDURE EVENTS (CONT)

Event: 1B. Surgery or other invasive procedure performed on the wrong patient

Additional Specifications: Defined as any surgery or invasive procedure on a patient that is not consistent with the correctly documented informed consent for that patient.

Surgery or other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, injection into joints.

Implementation Guidance: It should be noted that a correctly documented informed consent for patients whose procedures will not be carried out in an operating room may not involve a "surgical consent form"; however, it does require informed consent be documented in the patient record.

This event is intended to capture:

- surgical procedures (whether or not completed) initiated on one patient intended for a different patient.

Use of accepted patient identification procedures is key to avoiding such events.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

Event: 1C. Wrong surgical or other invasive procedure performed on a patient

Additional Specifications: Defined as any surgical or other invasive procedure performed on a patient that is not consistent with the correctly documented informed consent for that patient.

Surgery or other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, injection into joints.

Excludes emergent situations that occur in the course of surgery or other invasive procedures and/or whose exigency precludes obtaining informed consent.

Implementation Guidance: It should be noted that a correctly documented informed consent for patients whose procedures will not be carried out in an operating room may not involve a "surgical consent form"; however, it does require informed consent be documented in the patient record.

This event is intended to capture:

- insertion of the wrong medical implant into the correct surgical site.

This event is not intended to capture: changes in plan upon entry into the patient with discovery of pathology in close proximity to the intended place where risk of a second surgery/procedure outweighs benefit of patient consultation, or unusual physical configuration (for example adhesions, spine level/extra vertebrae).

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

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1. SURGICAL OR INVASIVE PROCEDURE EVENTS (CONT)

Event: 1D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure

Additional Specifications: Includes medical or surgical items intentionally placed by provider(s) that are unintentionally left in place.

Excludes a) objects present prior to surgery or other invasive procedure that are intentionally left in place; b) objects intentionally implanted as part of a planned intervention; and c) objects not present prior to surgery/procedure that are intentionally left in when the risk of removal exceeds the risk of retention (such as microneedles, broken screws).

Implementation Guidance: This event is intended to capture:

- occurrences of unintended retention of objects at any point after the surgery/procedure ends regardless of setting (post anesthesia recovery unit, surgical suite, emergency department, patient bedside) and regardless of whether the object is to be removed after discovery;
- unintentionally retained objects (including such things as wound packing material, sponges, catheter tips, trocars, guide wires) in all applicable settings.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

Event: 1E. Intraoperative or immediately postoperative/postprocedure death in an ASA Class I patient

Additional Specifications: Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.

Immediately post-operative means within 24 hours after surgery or other invasive procedure was completed or after administration of anesthesia (if surgery/procedure not completed).

Implementation Guidance: This event is intended to capture:

- ASA Class I patient death associated with the administration of anesthesia whether or not the planned surgical procedure was carried out.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices

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2: PRODUCT OR DEVICE EVENTS

Event: 2A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting

Additional Specifications: Includes contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.

Includes threat of disease that changes patient's risk status for life requiring medical monitoring not needed before the event

Implementation Guidance: This event is intended to capture:

- contaminations that can be seen with the naked eye or with use of detection mechanisms in general use. These contaminations are to be reported at such time as they become known to the provider or healthcare organization. Contaminants may be physical, chemical, or biological in nature. Not all contaminations can be seen with the naked eye (e.g., hepatitis and HIV) or readily detected using generally available or more specialized testing mechanisms (e.g., cultures, nucleic acid testing, mass spectrometry, and tests that signal changes in pH or glucose levels). Contamination that is inferred and changes risk status for life (e.g., consider a syringe or needle contaminated once it has been used to administer medication to a patient by injection or via connection to a patient's intravenous infusion bag or administration set).

This event is intended to capture:

- administration of contaminated vaccine or medication (e.g., intramuscular antibiotic);
- serious infection from contaminated drug or device used in surgery or an invasive procedure (e.g., a scalpel);
- occurrences related to use of improperly cleaned or maintained device.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

Event: 2B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended

Additional Specifications: Includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, ventilators, and procedural and monitoring equipment.

Implementation Guidance: This event is intended to capture:

- occurrences whether or not the use is intended or described by the device manufacturers' literature

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

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2. PRODUCT OR DEVICE EVENTS (CONT)

Event: 2C. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting

Additional Specifications: Excludes death or serious injury associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

Implementation Guidance: This event is intended to capture:

- high-risk procedures, other than neurosurgical procedures, that include, but are not limited to, procedures involving the head and neck, vaginal delivery and caesarean section, spinal instrumentation procedures, and liver transplantation;
- low-risk procedures, including those related to lines placed for infusion of fluids in vascular space,

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Long-term Care/Skilled Nursing Facilities

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3. PATIENT PROTECTION EVENTS

Event: 3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person.

Implementation Guidance: The terms “authorized” and “decision-making capacity” are defined in the glossary. Release to “other than an authorized person” includes removing the patient/resident without specific notification and approval by staff, even when the person is otherwise authorized.

Examples of individuals who do not have decision-making capacity include: newborns, minors, adults with Alzheimer’s,

Individual healthcare organizations or other relevant jurisdictional authorities may have specific requirements for assessing decision-making capacity.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

Event: 3B. Patient death or serious injury associated with patient elopement (disappearance).

Additional Specifications: Includes events that occur after the individual presents him/herself for care in a healthcare setting.

Excludes events involving competent adults with decision-making capacity who leave against medical advice or voluntarily leave without being seen.

Implementation Guidance: The term “elopement” and “competent” adult should be interpreted in accordance with prevailing legal standards in applicable jurisdictions.

Of note, an assessment that identifies patients at “risk” of elopement or a chief complaint and findings of risk accompanied by organizationally defined measures to be taken when risk is identified could be useful in both prevention and event analysis.

This is not intended to capture:

- death or serious injury that occurs (after the patient is located) due to circumstances unrelated to the elopement.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

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3. PATIENT PROTECTION EVENTS (CONT)

Event: 3C. Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting

Additional Specifications: Includes events that result from patient actions after they present themselves for care in a healthcare setting.

Excludes deaths resulting from self-inflicted injuries that were the reason for admission/presentation to the healthcare facility.

Implementation Guidance: This event is not intended to capture patient suicide or attempted suicide when the patient is not physically present in the "healthcare setting" as defined in the glossary.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

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4. CARE MANAGEMENT EVENTS

Event: 4A. Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)

Additional Specifications: Excludes reasonable differences in clinical judgment on drug selection and dose.

Includes, but is not limited to, death or serious injury associated with: a) over- or under-dosing; b) administration of a medication to which a patient has a known allergy or serious contraindication, c) drug-drug interactions for which there is known potential for death or serious injury, and d) improper use of single-dose/single-use and multi-dose medication vials and containers leading to death or serious injury as a result of dose adjustment problems.

Implementation Guidance: This event is intended to capture:

- the most serious medication errors including occurrences in which a patient receives a medication for which there is a contraindication, or a patient known to have serious allergies to specific medications/agents, receives those medications/agents, resulting in serious injury or death. These events may occur as a result of failure to collect information about contraindications or allergies, failure to review such information available in information systems, failure of the organization to ensure availability of such information and prominently display such information within information systems, or other system failures that are determined through investigation to be cause of the adverse event;
- occurrences in which a patient dies or suffers serious injury as a result of failure to administer a prescribed medication;
- occurrences in which a patient is administered an over- or under-dose of a medication including insulin, heparin, and any other high alert medication including but not limited to medications listed on the Institute for Safe Medication Practices "High Alert Medication List";
- occurrences in which a patient dies or suffers serious injury as a result of wrong administration technique.

This event is not intended to capture:

- patient death or serious injury associated with allergies that could not reasonably have been known or discerned in advance of the event.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

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4. CARE MANAGEMENT EVENTS (CONT)

Event: 4B. Patient death or serious injury associated with unsafe administration of blood products

Implementation Guidance: Unsafe administration includes, but is not limited to, hemolytic reactions and administering; a) blood or blood products to the wrong patient; b) the wrong type; or c) blood or blood products that have been improperly stored or handled.

This event is not intended to capture:

- patient death or serious injury associated with organ rejection other than those attributable to a hyperacute hemolytic reaction
- patient death or injury when cause is not detectable by ABO/HLA matching.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facility

Event: 4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting

Additional Specifications: Includes events that occur within 42 days post-delivery.

Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.

Implementation Guidance: This event is not intended to create a new obligation. The organization's obligation, under this event, is to report only maternal death or serious injury associated with labor or delivery in a low risk pregnancy when made aware of the maternal death or serious injury either by readmittance or by the patient's family.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers

Event: 4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy

Additional Specifications: Includes, for the office-based surgery, birthing center or "home" setting, unplanned admission to an inpatient setting within 24 hours of delivery

Implementation Guidance: Unplanned admission to other than the birth setting should be verified with the identified birth setting.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers

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4. CARE MANAGEMENT EVENTS (CONT)

Event: 4E. Patient death or serious injury associated with a fall while being cared for in a healthcare setting

Additional Specifications: Includes but is not limited to fractures, head injuries, and intracranial hemorrhage

Implementation Guidance: Of note, an assessment that identifies patients at “risk” of fall, findings of risk accompanied by organizationally defined measures to be taken when risk is identified could be useful in both prevention and event analysis.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

Event: 4F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting

Additional Specifications: Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission and excludes pressure ulcers that develop in areas where deep tissue injury is documented as present on admission/presentation.

Implementation Guidance: Although this event could occur in the ambulatory surgery environment based on patient condition and surgery time, it will be difficult to discern. Pre- and post-skin assessment will be key.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Long-term Care/Skilled Nursing Facilities

Event: 4G. Artificial insemination with the wrong donor sperm or wrong egg

Implementation Guidance: The organization’s obligation is to report the event when made aware of the occurrence.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices

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4. CARE MANAGEMENT EVENTS (CONT)

Event: 4H. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen.

Additional Specifications: Includes events where specimens are misidentified, where another procedure cannot be done to produce a specimen

Includes progression of an undiagnosed disease or threat of disease that changes the patient's risk status for life, requiring monitoring not needed before the event

Implementation Guidance: This event is not intended to capture:

- procedures where the specimen was properly handled, but the specimen proved to be nondiagnostic,

Inability to secure a replacement for a lost specimen can occur with excisional biopsy as well as in organ removal.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

Event: 4I. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results.

Additional Specifications: Includes events where failure to report increased neonatal bilirubin levels result in kernicterus.

Implementation Guidance: Examples of serious injury are a new diagnosis, or an advancing stage of an existing diagnosis (e.g., cancer).

Failure to follow up or communicate can be limited to healthcare staff or can involve communication to the patient.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

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5. ENVIRONMENTAL EVENTS

Event: 5A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting

Additional Specifications: Excludes events involving patients during planned treatments such as electric countershock/elective cardioversion,

Implementation Guidance: This event is intended to capture:

- patient death or injury associated with unintended electric shock during the course of care or treatment;
- staff death or injury associated with unintended electric shock while carrying out duties directly associated with a patient care process, including preparing for care delivery.

This event is not intended to capture:

- patient death or injury associated with emergency defibrillation in ventricular fibrillation or with electroconvulsive therapies;
- injury to staff who are not involved in patient care.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

Event: 5B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances

Implementation Guidance: This event is intended to capture:

events in which the line is attached to a reservoir distant from the patient care unit or in a tank near the patient such as E-cylinders, anesthesia machines,

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

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5. ENVIRONMENTAL EVENTS (CONT.)

Event: 5C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting

Implementation Guidance: This event is intended to capture burns that result from:

- operating room flash fires, including second-degree burn in those cases;
- hot water;
- sunburn in the patient with decreased ability to sense pain;
- smoking in the patient care environment.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

Event: 5D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting

Implementation Guidance: The event is intended to capture:

- instances where physical restraints are implicated in the death, e.g., lead to strangulation/entrapment, etc.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

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6. RADIOLOGIC EVENTS

Event: 6A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area

Additional Specifications: Includes events related to material inside the patient's body or projectiles outside the patient's body.

Implementation Guidance: This event is intended to capture injury or death as a result of projectiles including:

- retained foreign object
- external projectiles
- pacemakers

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices

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7. POTENTIAL CRIMINAL EVENTS

Event: 7A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider

Implementation Guidance: This event is intended to capture:

- those without licensure to provide the care given;
- those with licensure who represent themselves and act beyond the scope of their licensure,

It is not intended to capture individuals who are practicing within the scope of their license on whom patients or others mistakenly bestow titles beyond that scope when such is not encouraged by the provider

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

Event: 7B. Abduction of a patient/resident of any age

Implementation Guidance: This event is intended to capture:

- removal of a patient/resident, who does not have decisionmaking capacity, without specific notification and approval by staff even when the person is otherwise authorized to be away from the setting.

Examples of individuals who do not have decisionmaking capacity include: newborns, minors, adults with Alzheimer's.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

Appendix A - Specifications of the Serious Reportable Events In Healthcare—2011 Update

7. POTENTIAL CRIMINAL EVENTS (CONT.)

Event: 7C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting

Implementation Guidance: Language and definitions may vary based on state statute; however, the principle and intent remain regardless of language required based on jurisdiction.

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

Event: 7D. Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting.

Implementation Guidance: Language and definitions may vary based on state statute (e.g., many states have existing statutes that use the terms “first degree assault” or “second degree assault” or “battery”).

Applicable settings:

- Hospitals
- Outpatient/Office-based Surgery Centers
- Ambulatory Practice Settings/Office-based Practices
- Long-term Care/Skilled Nursing Facilities

1. SURGICAL EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE ¹
A. Surgery performed on the wrong body part	<p>Defined as any surgery performed on a body part that is not consistent with the correctly documented informed consent for that patient.²</p> <p>Surgery includes endoscopies and other invasive procedures.</p> <p>Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.</p>	<p>This event is intended to capture:</p> <ul style="list-style-type: none"> • Surgery on the right body part, but on the wrong location on the body; for example, left versus right (appendages and/or organs), level (spine). • Wrong site surgery, even if corrected intraoperatively, as long as the surgery had begun, based on the definition below. <p>This event is not intended to capture:</p> <ul style="list-style-type: none"> • Changes in plan upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefits of patient consultation; or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra-vertebrae). <p><i>Surgery</i> is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. <i>Surgeries</i> include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as endoscopes or procedures such as drawing blood.</p> <p>Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used.</p> <p><i>Surgery begins</i> regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs.</p> <p><i>Surgery ends</i> after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting (e.g., postanesthesia recovery unit, surgical suite, endoscopy unit).</p> <p>Although an incorrectly placed surgical mark could result in surgery being performed on the wrong body part, surgery does not begin at the time a surgical mark is made on the patient. Placing a mark on the wrong body part does not in itself constitute wrong site surgery.</p> <p style="text-align: right;">(more)</p>

¹Implementation guidance amplifies statements in the event and additional specifications based on the experience of those organizations/entities that have implemented the reporting of the events and the recommendations of NQF Members and the public. As such, the guidance does not purport to be—nor is it required to be—either comprehensive or uniform across the events.

²Except in the case of an emergency, a physician must obtain a patient's agreement (informed consent) to any course of treatment. Physicians are required to tell the patient anything that would substantially affect his or her decision. Such information typically includes the nature and purpose of the treatment, including its risks and benefits, and alternative courses of treatment, including risks and benefits. The American Medical Association definition of informed consent is "a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention" (see www.ama-assn.org/ama/pub/category/1608.html).

1. SURGICAL EVENTS (continued)

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
B. Surgery performed on the wrong patient	<p>Defined as any surgery on a patient that is not consistent with the correctly documented informed consent for that patient.</p> <p>Surgery includes endoscopies and other invasive procedures.</p>	<p>This event is intended to capture:</p> <ul style="list-style-type: none"> ■ Surgical procedures (whether or not completed) initiated on one patient that were intended for a different patient. <p><i>Surgery</i> is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. <i>Surgeries</i> include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as otoscopes or procedures such as drawing blood.</p> <p>Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used.</p> <p><i>Surgery begins</i>, regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs.</p> <p><i>Surgery ends</i> after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting (e.g., postanesthesia recovery unit, surgical suite, endoscopy unit).</p>

1. SURGICAL EVENTS (continued)

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
C. Wrong surgical procedure performed on a patient	<p>Defined as any surgical procedure performed on a patient that is not consistent with the correctly documented informed consent for that patient.</p> <p>Surgery includes endoscopies and other invasive procedures.</p> <p>Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.</p>	<p>This event is intended to capture:</p> <ul style="list-style-type: none"> ■ Insertion of the wrong medical implant into the correct surgical site. <p>This event is not intended to capture:</p> <ul style="list-style-type: none"> ■ Changes in plan upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation; or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae). <p><i>Surgery</i> is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. <i>Surgeries</i> include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as otoscopes or procedures such as drawing blood.</p> <p>Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used.</p> <p><i>Surgery begins</i>, regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs.</p> <p><i>Surgery ends</i> after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting (e.g., surgical suite, endoscopy unit).</p>

(more)

1. SURGICAL EVENTS (continued)

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
D. Unintended retention of a foreign object in a patient after surgery or other procedure	Excludes a) objects present prior to surgery that are intentionally left in place; b) objects intentionally implanted as part of a planned intervention; and c) objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention (such as microneedles, broken screws).	<p>This event is intended to capture:</p> <ul style="list-style-type: none"> ■ Occurrences of unintended retention of objects at any point after the surgery ends, regardless of setting or of whether the object is removed. <p><i>Surgery</i> is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. Surgeries include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include the use of instruments such as otoscopes or procedures such as drawing blood.</p> <p>Organizations may choose to adopt a list of surgical procedures to supplement the definition above; for example, the Institute of Clinical Systems Improvement list of procedures is commonly used.</p> <p><i>Surgery begins</i>, regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs.</p> <p><i>Surgery ends</i> after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting (e.g., postanesthesia recovery unit, surgical suite, endoscopy unit).</p>

(more)

2. PRODUCT OR DEVICE EVENTS

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	Includes detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.	The term <i>detectable</i> is intended to capture contaminations that can be seen with the naked eye or with the use of detection mechanisms that are in general use; these contaminations are to be reported when they become known to the provider or healthcare facility. Detection mechanisms may include cultures and tests that signal changes in pH or glucose levels.
B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended	Includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps, and ventilators.	This event is intended to capture occurrences whether or not the use is intended or described by the device manufacturers' literature. The Food and Drug Administration defines medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including a component part or accessory which is: <ul style="list-style-type: none"> ■ recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; ■ intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or ■ intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."
C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	Excludes death or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.	High-risk procedures, other than neurosurgical procedures, that include a small but known risk of air embolism are reportable under this event, including, but not limited to, those involving the head and neck, vaginal delivery and cesarean section, spinal instrumentation procedures, and liver transplantation.

(more)

3. PATIENT PROTECTION EVENTS

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
A. Infant discharged to the wrong person		Stedman's Online Medical Dictionary defines an infant as a child under the age of one year.
B. Patient death or serious disability associated with patient elopement (disappearance)	Excludes events involving competent adults.	This event is not intended to capture death or serious disability that occurs due to circumstances unrelated to the elopement (after the patient is located). The term <i>competent adult</i> should be interpreted in accordance with prevailing legal standards.
C. Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility	Defined as events that result from patient actions after admission to a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility.	This event is not intended to capture patient suicide or attempted suicide when the patient is not physically present in the "healthcare facility" (defined in box B, previously).

4. CARE MANAGEMENT EVENTS

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)	Excludes reasonable differences in clinical judgment involving drug selection and dose. Includes administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability.	This event is intended to capture: <ul style="list-style-type: none"> ■ The most serious medication errors, including occurrences in which a patient known to have serious allergies to specific medications/agents receives those medications/agents, resulting in serious harm or death. These events may occur as a result of failure to collect allergy information; failure to review available allergy information; failure to assure the availability of allergy information and prominently display it; or through other system failures that are determined by investigation to be the cause of the adverse event. ■ Occurrences in which a patient dies or suffers serious disability as a result of failure to administer a prescribed medication. ■ Occurrences in which a patient dies or suffers serious disability as a result of the wrong administration technique. This event is not intended to capture: <ul style="list-style-type: none"> ■ Patient death or serious disability associated with allergies that could not reasonably have been known or discerned in advance of the event. ■ All situations in which two or more medications are administered for which there are drug-drug interactions with known potential for death or serious disability—only those that result in death or serious disability.
B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products		This event is not intended to capture: <ul style="list-style-type: none"> ■ Patient death or disability associated with organ rejection, other than those attributable to a hyperacute hemolytic reaction. ■ Patient death or disability when the cause is not detectable by ABO/HLA matching.

(more)

4. CARE MANAGEMENT EVENTS

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	Includes events that occur within 42 days postdelivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.	This event is not intended to create a new obligation; the organization's obligation is to report the event when it is made aware of the maternal death or serious disability either by re-admittance or by the patient's family. A low-risk pregnancy is defined as a pregnancy occurring in a woman aged 18-39 who has no previous diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome. ¹⁰
D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility		Hypoglycemia is defined as blood glucose levels <60 mg/dL (ICD-9, 251.0).
E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	<i>Hyperbilirubinemia</i> is defined as bilirubin levels >30 mg/dL. <i>Neonate</i> refers to the first 28 days of life.	The organization's obligation is to report the event when it is made aware of the death or serious disability either by re-admittance or by the patient's family.
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	Excludes progression from Stage 2 to Stage 3, if Stage 2 was recognized upon admission.	
G. Patient death or serious disability due to spinal manipulative therapy		Spinal manipulative therapy encompasses all types of manual techniques, including spinal mobilization (movement of a joint within its physiologic range of motion) and manipulation (movement beyond its physiologic range of motion), regardless of their precise anatomic and physiologic focus or their discipline of origin. ¹¹
H. Artificial insemination with the wrong donor sperm or wrong egg		The organization's obligation is to report the event when it is made aware of the occurrence.

(more)

¹⁰NQF, *Serious Reportable Events in Healthcare: A Consensus Report*, NQF, Washington, DC, 2002¹¹NQF, *Serious Reportable Events in Healthcare: A Consensus Report*, NQF, Washington, DC, 2002

5. ENVIRONMENTAL EVENTS

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility	Excludes events involving planned treatments such as electric countershock/elective cardioversion.	<p>This event is intended to capture:</p> <ul style="list-style-type: none"> ■ Patient death or disability associated with unintended electric shock during the course of care or treatment. <p>This event is not intended to capture:</p> <ul style="list-style-type: none"> ■ Patient death or disability associated with emergency defibrillation during ventricular fibrillation or electroconvulsive therapies.
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances		
C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility		
D. Patient death or serious disability associated with a fall while being cared for in a healthcare facility	Includes but is not limited to fractures, head injuries, and intracranial hemorrhage.	
E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility		<p>The event is intended to capture instances in which restraints are implicated in the death; for example, the use led to strangulation/entrapment. Death/disability resulting from falls caused by lack of restraints would be captured under falls.</p> <p>Restraint is currently defined by the Joint Commission, by the Centers for Medicare and Medicaid Services, and by some states. If none of those definitions apply to an institution, the following definition, which is intended to comprise definitions from the named organizations, is offered: Restraint is defined as any method of restricting a patient's freedom of movement that is not a usual and customary part of a medical diagnostic or treatment procedure to which the patient or his or her legal representative has consented; that is not indicated to treat the patient's medical condition or symptoms; or that does not promote the patient's independent functioning.¹</p>

(more)

¹ Adapted from the Joint Commission, Comprehensive Accreditation Manual *Refreshed Core*, 2006.

6. CRIMINAL EVENTS

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider		
B. Abduction of a patient of any age		
C. Sexual assault on a patient within or on the grounds of a healthcare facility		Language and definitions may vary based on state statute (e.g., many states have existing statutes that may use the terms <i>sexual assault</i> or <i>simple assault</i> or <i>criminal sexual conduct</i>); however, the principle and intent remain regardless of the language required based on jurisdiction.
D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility		Language and definitions may vary based on state statute (e.g., many states have existing statutes that use the terms <i>first degree assault</i> or <i>second degree assault</i> or <i>battery</i>).

Notice of Agency Rule-making Proposal

AGENCY: DHHS, Division of Licensing and Regulatory Services

CHAPTER NUMBER AND TITLE:

10-144 C.M.R. Ch 114, Rules Governing the Reporting of Sentinel Events

PROPOSED RULE NUMBER *(leave blank; assigned by Secretary of State)*:

CONTACT PERSON FOR THIS FILING:

Kenneth Albert, RN, Esq., Director, Division of Licensing and Regulatory Services

41 Anthony Ave, 11 State House Station, Augusta, Maine 04333

(207) 287-9300 (800) 791-4080 fax: (207) 287-5807 kenneth.albert@maine.gov

CONTACT PERSON FOR SMALL BUSINESS INFORMATION (if different): Same

PUBLIC HEARING (if any): None scheduled.

COMMENT DEADLINE: October 19, 2012 at 5 pm

BRIEF *SUMMARY:

- The proposed rules replace the outdated 2007 NQF list of serious reportable events with the 2011 updated list published by the National Quality Forum (NQF). The 2011 NQF list includes the following changes: [1] A NEW category is added to the NQF list: "Radiologic Events" is now Category 6; [2] A NEW event is added at Category 1E: patient death associated with the administration of anesthesia; [3] The event in Category 3A is expanded to include the discharge or release (to other than an authorized person) of a person "of any age who is unable to make decisions" (the word "infant" is deleted); [4] The event in Category 3C is expanded to include "self-harm" (Patient suicide, attempted suicide or self-harm); [5] A number of changes are made to Category 4 including the following: three events in the 2007 list are not in the 2011 list (deletes hypoglycemia, hyperbilirubinemia, and spinal manipulative therapy); there are three NEW events (4D - death or serious injury of a neonate associated with labor or deliver in a low-risk pregnancy; 4H - death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen; and 4I - death or serious injury resulting from failure to follow up or communicate laboratory pathology or radiology test results); [6] An event was moved out of Category 5 and into Category 4E (death or serious injury associated with a fall); and [7] An event in Category 7C is expanded to include the underlined words: (Sexual abuse/assault on a patient or staff member).
- The definitions of "Serious" and "Surgery" have been updated for consistency with the 2011 NQF events. See Sections 1.24 and 1.27.
 - The department also made non-substantive changes to this rule including: [1] implementing the federal change of the term ICF/MR (Intermediate Care Facilities for Persons with Mental Retardation) to ICF/IID (Intermediate Care Facility for Individuals who are Intellectually Disabled); and [2] updated reference to the 2011 NQF list of serious reportable events. See

Sections 1.8.4 and 1.22.4.

IMPACT ON MUNICIPALITIES OR COUNTIES (if any)

This rule is not expected to fiscally impact or create new recording burdens for health care facilities. This rule is not expected to yield new costs for municipal or county governments.

STATUTORY AUTHORITY FOR THIS RULE:

22 M.R.S.A. Chapter 1684 Sentinel Events Reporting; 22 M.R.S.A. §42; and 22-A M.R.S.A. §205.

SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED (if different): Not different.

E-MAIL FOR OVERALL AGENCY RULE-MAKING LIAISON: Kevin.Wells@maine.gov

* Check one of the following two boxes.

☒ The above summary is for use in both the newspaper and website notices.

☐ The above summary is for the newspaper notice only. A more detailed summary / basis statement is attached.

Please approve bottom portion of this form and assign appropriate AdvantageME number.

APPROVED FOR PAYMENT

DATE: 9-11-2012

(Authorized signature) Kenneth Albert, RN, Esq., Director

Division of Licensing and Regulatory Services



**Department of Health
and Human Services**

*Maine People Living
Safe, Healthy and Productive Lives*

Paul R. LePage, Governor

Mary C. Mayhew, Commissioner

Department of Health and Human Services
Licensing and Regulatory Services
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Augusta, Maine 04333-0011
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DATE: September 18, 2012

TO: Interested Parties

FROM: Kenneth Albert, RN, Esq., Director, Division of Licensing and Regulatory Services

SUBJECT: Proposed Rules Governing the Reporting of Sentinel Events, 10-144 C.M.R. Ch 114.
No public hearing.
Comment Deadline: October 19, 2012 at 5 pm

The proposed rules replace the outdated 2007 NQF list of serious reportable events with the 2011 updated list published by the National Quality Forum (NQF).

- The 2011 NQF list includes the following changes:
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The proposed rule is posted at <http://www.maine.gov/dhhs/dlrs/rulemaking/proposed.shtml> Call (207) 287-9300 to have a paper copy of the rule mailed to you.

Comments on the proposed rules will be accepted until Friday, October 19, 2012 at 5 pm.

Thank you.